

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 1. (Currently Amended) A computer-implemented method of identifying
2 whether a patient test sample is associated with one or more of a plurality of specific systemic
3 autoimmune diseases (SADs) based on autoantibody levels present in the patient test sample; the
4 method comprising:

5 storing a plurality of reference data sets in a memory, each reference data set
6 having quantitative values representing levels for each of a plurality of specific autoantibodies,
7 wherein said reference data sets include, for each of said plurality of specific SADs, at least one
8 reference data set for the specific SAD, and wherein said reference data sets include at least one
9 reference data set associated with none of the specific SADs;

10 receiving, in a computer system, a sample data set having quantitative values
11 representing levels for each of said plurality of autoantibodies for a patient test sample; and
12 automatically applying, in the computer system, a k-nearest neighbor process to
13 the quantitative values of the sample data set and the reference data sets to produce a statistically
14 derived decision indicating whether, out of a range of none, one [[or]] and more than one of said
15 systemic autoimmune diseases, the patient test sample is associated with [[none,]] one or more
16 of said specific [[SADs;]] SADs, wherein if the decision identifies more than one SAD, the
17 patient test sample is considered equally likely to have said identified SADs; and

18 providing the statistically derived decision as output, the decision identifying
19 which one or more of the of said systemic autoimmune diseases the patient test sample is
20 associated with if the statistically derived decision indicates that the patient test sample is
21 associated with one or more of said systemic autoimmune diseases.

2. (Original) The computer-implemented method of claim 1, wherein the
SADs include two or more systemic autoimmune diseases selected from the group consisting of

- 3 systemic lupus erythematosus, scleroderma (SLE), Sjögren's syndrome (SS), polymyositis
4 (PMYO), dermatomyositis (DMYO), CREST, and mixed connective tissue disease (MCTD).

1 3. (Original) The computer-implemented method of claim 1, wherein the
2 SADs include two or more systemic autoimmune diseases selected from the group consisting of
3 systemic lupus erythematosus (SLE), scleroderma, Sjögren's syndrome (SS), myositis (MYO),
4 polymyositis (PMYO), dermatomyositis (DMYO), CREST, connective tissue disease (CTD),
5 fibromyalgia, osteoarthritis (OA), Reynaud's syndrome and Rheumatoid arthritis (RA).

1 4. (Original) The computer-implemented method of claim 1, wherein said
2 plurality of autoantibodies comprises antibodies to at least ten of the following antigens:

3 SSA 60,
4 SSA 52,
5 SSB 48,
6 Sm BB',
7 Sm D1,
8 Sm,
9 SmRNP
10 RNP 68,
11 RNP A,
12 RNP C,
13 Fibrillarin,
14 Riboproteins P0, P1, and P2,
15 dsDNA,
16 Nucleosome,
17 Ku,
18 Centromere A,
19 Centromere B,
20 Scl-70,
21 Pm-Scl,

22 RNA-Polymerases 1, 2, and 3,
23 Th,
24 Jo-1,
25 Mi-2,
26 PL7,
27 PL12, and
28 SRP.

1 5. (Original) The computer-implemented method of claim 1, wherein said
2 plurality of autoantibodies consists of antibodies to the following antigens:

3 SSA 60,
4 SSA 52,
5 SSB 48,
6 Sm,
7 SmRNP,
8 RNP 68,
9 RNP A,
10 Riboproteins P0, P1, and P2,
11 dsDNA,
12 Nucleosome,
13 Centromere B,
14 Scl-70, and
15 Jo-1.

1 6. (Previously Presented) The computer-implemented method of claim 1,
2 wherein providing includes generating a display output including said indication of whether the
3 patient test sample is associated with none, one or more of the specific SADs.

1 7. (Original) The computer-implemented method of claim 6, wherein
2 generating includes transmitting display output data to a remote computer system and rendering
3 the display output on a display screen coupled with the remote computer system.

1 8. (Original) The computer-implemented method of claim 1, wherein
2 receiving includes receiving the sample data set from an automated test system over a network
3 connection.

1 9. (Original) The computer-implemented method of claim 8, wherein storing
2 includes receiving the reference data sets from the automated test system over the network
3 connection.

1 10. (Original) The computer-implemented method of claim 1, wherein storing
2 includes receiving the reference data sets from one or more test sources.

1 11. (Original) The computer-implemented method of claim 1, wherein the k-
2 nearest neighbor process includes determining, for each of the reference data sets, a concordance
3 value between the sample data set and the reference data set, and comparing each concordance
4 value to a threshold value, wherein only a first plurality of the reference data sets having a
5 concordance value that exceeds the threshold value are used by the process.

1 12. (Original) The computer-implemented method of claim 11, wherein the k-
2 nearest neighbor process further includes determining, for each of the reference data sets, a
3 distance metric value between the sample data set and the reference data set.

1 13. (Original) The computer-implemented method of claim 11, wherein the
2 process further includes:
3 determining whether the number of the first plurality of reference data sets
4 exceeds a minimum cutoff value, and

5 if not, providing an indication that the patient test sample is associated with none
6 of the specific SADs, and
7 if so, determining whether the patient test sample is associated with one or more
8 of the specific SADs.

1 14. (Original) The computer-implemented method of claim 11, wherein the
2 process further includes determining a disease concordance value for each of the first plurality of
3 reference data sets.

1 15. (Original) The computer-implemented method of claim 14, wherein
2 determining a disease concordance value includes:
3 for each SAD associated with the first plurality of reference data sets:
4 adding the number of the first plurality of reference data sets associated with that
5 SAD and dividing by the total number of the first plurality of reference data sets to produce a
6 disease concordance value for that SAD.

1 16. (Original) The computer-implemented method of claim 15, further
2 including comparing each disease concordance value with a first threshold value, and returning
3 the SAD associated with the concordance value that exceeds the first threshold value.

1 17. (Original) The computer-implemented method of claim 16, further
2 including comparing each disease concordance value with a second threshold value, and
3 returning the SAD associated with the concordance value that exceeds the second threshold
4 value.

1 18. (Currently Amended) A computer system configured to provide output
2 data indicating whether a patient test sample is associated with one or more of a plurality of
3 specific systemic autoimmune diseases (SADs) based on autoantibody levels present in the
4 patient test sample; the system comprising:
5 a memory module that stores a plurality of reference data sets, each reference data
6 set having quantitative values representing levels for each of a plurality of specific

7 autoantibodies, wherein said reference data sets include, for each of said plurality of specific
8 SADs, at least one reference data set for the specific SAD, and wherein said reference data sets
9 include at least one reference data set associated with none of the specific SADs;

10 a means for receiving a sample data set having quantitative values representing
11 levels for each of said plurality of autoantibodies for a patient test sample;

12 a processor configured to analyze the sample data set and the reference data sets
13 by applying a k-nearest neighbor process to the quantitative values of the sample data set and the
14 reference data sets to produce a statistically derived decision indicating whether, out of a range
15 of none, one [[or]] and more than one of said systemic autoimmune diseases, the patient test
16 sample is associated with none, one or more of said specific [[SADs;]] SADs, wherein if the
17 decision identifies more than one SAD, the patient test sample is considered equally likely to
18 have said identified SADs; and

19 a means for providing output data including the statistically derived decision, the
20 decision identifying which one or more of the of said systemic autoimmune diseases the patient
21 test sample is associated with if the statistically derived decision indicates that the patient test
22 sample is associated with one or more of said systemic autoimmune diseases.

1 19. (Original) The system of claim 18, wherein the SADs include two or
2 more systemic autoimmune diseases selected from the group consisting of systemic lupus
3 erythematosus (SLE), scleroderma, Sjögren's syndrome (SS), myositis (MYO), polymyositis
4 (PMYO), dermatomyositis (DMYO), CREST, connective tissue disease (CTD), fibromyalgia,
5 osteoarthritis (OA), Reynaud's syndrome and Rheumatoid arthritis (RA).

1 20. (Original) The system of claim 18, wherein said plurality of
2 autoantibodies comprises antibodies to at least ten of the following antigens:

3 SSA 60,
4 SSA 52,
5 SSB 48,
6 Sm BB',
7 Sm D1,

8 Sm,
9 SmRNP,
10 RNP 68,
11 RNP A,
12 RNP C,
13 Fibrillarin,
14 Riboproteins P0, P1, and P2,
15 dsDNA,
16 Nucleosome,
17 Ku,
18 Centromere A,
19 Centromere B,
20 Scl-70,
21 Pm-Scl,
22 RNA-Polymerases 1, 2, and 3,
23 Th,
24 Jo-1,
25 Mi-2,
26 PL7,
27 PL12, and
28 SRP.

1 21. (Original) The system of claim 18, wherein said plurality of
2 autoantibodies consists of antibodies to the following antigens:

3 SSA 60,
4 SSA 52,
5 SSB 48,
6 Sm,
7 SmRNP,

8 RNP 68,
9 RNP A,
10 Riboproteins P0, P1, and P2,
11 dsDNA,
12 Nucleosome,
13 Centromere B,
14 Scl-70, and
15 Jo-1.

1 22. (Original) The system of claim 18, wherein the means for providing the
2 output data includes one of a monitor for displaying the output data, a printer for printing the
3 output data and a communication interface device for providing the output data to a separate
4 computer system.

1 23. (Original) The system of claim 18, wherein the means for receiving the
2 sample data set includes one of an interface device configured to receive data from a remote
3 automated test system, a manual input device, and a device configured to read data from a
4 computer readable medium.

1 24. (Previously Presented) The system of claim 18, wherein the memory
2 module includes one of a RAM, a ROM, a computer readable disk medium, a hard disk drive and
3 a separate database system.

1 25. (Original) The system of claim 18, wherein the k-nearest neighbor
2 process determines, for each of the reference data sets, a concordance value between the sample
3 data set and the reference data set, and compares each concordance value to a threshold value,
4 wherein only a first plurality of the reference data sets having a concordance value that exceeds
5 the threshold value are used by the process.

1 26. (Original) The system of claim 25, wherein the k-nearest neighbor
2 process further determines, for each of the reference data sets, a distance metric value between
3 the sample data set and the reference data set.

1 27. (Original) The system of claim 25, wherein the k-nearest neighbor
2 process further determines whether the number of the first plurality of reference data sets
3 exceeds a minimum cutoff value, and
4 if not, provides an indication that the patient test sample is associated with none
5 of the specific SADs, and
6 if so, determines whether the patient test sample is associated with one or more of
7 the specific SADs.

1 28. (Original) The system of claim 25, wherein the k-nearest neighbor
2 process further determines a disease concordance value for each of the first plurality of reference
3 data sets.

1 29. (Original) The system of claim 28, wherein a disease concordance value
2 is determined for each SAD associated with the first plurality of reference data sets by adding the
3 number of the first plurality of reference data sets associated with that SAD and dividing by the
4 total number of the first plurality of reference data sets to produce a disease concordance value
5 for that SAD.

1 30. (Original) The system of claim 29, wherein the process further compares
2 each disease concordance value with a first threshold value, and returns the SAD associated with
3 the concordance value that exceeds the first threshold value.

1 31. (Original) The system of claim 30, wherein the process further compares
2 each disease concordance value with a second threshold value, and returns the SAD associated
3 with the concordance value that exceeds the second threshold value.

1 32. (Currently Amended) A computer-implemented method of identifying
2 whether a patient test sample is equally likely to be associated with more than one of a plurality
3 of specific systemic autoimmune diseases (SADs) based on autoantibody levels present in the
4 patient test sample; the method comprising:

5 storing a plurality of reference data sets in a memory, each reference data set
6 having values representing levels for each of a plurality of specific autoantibodies, wherein said
7 reference data sets include, for each of said plurality of specific SADs, at least one reference data
8 set for the specific SAD, and wherein said reference data sets include at least one reference data
9 set associated with none of the specific SADs;

10 receiving, in a computer system, a sample data set having values representing
11 levels for each of said plurality of autoantibodies for a patient test sample; and
12 automatically applying, in the computer system, a k-nearest neighbor process to
13 the sample data set and the reference data sets to produce a statistically derived decision
14 indicating whether, out of a range of none, one [[or]] and more than one of said systemic
15 autoimmune diseases, the patient test sample is associated with more than one of said specific
16 [[SADs;]] SADs, wherein if the decision identifies more than one SAD, the patient test sample is
17 considered equally likely to have said identified SADs; and

18 providing the statistically derived decision as output, the decision identifying
19 which of the more than one of said systemic autoimmune diseases the patient test sample is
20 associated with if the statistically derived decision indicates that the patient test sample is
21 associated with more than one of said systemic autoimmune diseases.

1 33. (New) A computer-implemented method of identifying whether a patient
2 test sample is associated with one or more of a plurality of specific systemic autoimmune
3 diseases (SADs) based on autoantibody levels present in the patient test sample; the method
4 comprising:

5 storing a plurality of reference data sets in a memory, each reference data set
6 having quantitative values representing levels for each of a plurality of specific autoantibodies,
7 wherein said reference data sets include, for each of said plurality of specific SADs, at least one

- 8 reference data set for the specific SAD, and wherein said reference data sets include at least one
9 reference data set associated with none of the specific SADs;
- 10 receiving, in a computer system, a sample data set having quantitative values
11 representing levels for each of said plurality of autoantibodies for a patient test sample; and
12 automatically applying, in the computer system, a k-nearest neighbor process to
13 the quantitative values of the sample data set and the reference data sets to produce a non-ranked
14 statistically derived decision indicating whether, out of a range of none, one and more than one
15 of said systemic autoimmune diseases, the patient test sample is associated with one or more of
16 said specific SADs, wherein if the decision identifies more than one SAD, the patient test sample
17 is considered equally likely to have said identified SADs; and
18 providing the statistically derived decision as output, the decision identifying
19 which one or more of said systemic autoimmune diseases the patient test sample is associated
20 with if the statistically derived decision indicates that the patient test sample is associated with
21 one or more of said systemic autoimmune diseases.